

**FACTORS ASSOCIATED TO LATENT TUBERCULOSIS INFECTION  
TREATMENT ADHERENCE IN CLINIC POPULATION, LEXINGTON FAYETTE  
COUNTY HEALTH DEPARTMENT, KY, USA.**

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**Abstract**

Adherence to Latent Tuberculosis Infection (LTBI) treatment is fundamental in reaching the *Healthy People 2020* goal to reduce TB disease to 1.0 per 100,000 populations. This study examined the completion rates among those who started treatment of LTBI with regimens containing INH or RIF and identified factors associated with completing treatment for LTBI. All Lexington Fayette County Health Department (LFCHD) patients who started treatment of LTBI regimens containing either INH or RIF during July 2012 and estimated to finish the treatment in April 2014 were studied. LTBI treatment completion rates were described and compared according to patient socio-demographic and other TB risk factors characteristics using univariate analysis and logbinomial regression. A total of 110 patients started LTBI treatment, 76 patients completed the treatment with completion rate 69.1%. RIF had 2.8 times higher odds of adherence to treatment (CI=1.1, 6.7). People who were born in Asia were more likely to complete the treatment (44.7%, aRR = 0.12, 95% CI= 1.2, 10.7) and surprisingly health workers were less likely to finish LTBI treatment. Shorter treatment increased completion rates. Although the reasons were not clearly identified, family support could be one of the reasons of a high completion rate. Delivering care door to door by community health worker (CHW) can be a priority alternative. Greater focus is needed to health workers by enforcing the policy in health facility.

**Keywords:** Adherence to treatment, Community Health Worker, completion rates, Latent Tuberculosis Infection.

**BACKGROUND**

Approximately one-third of the world's population is infected with *Mycobacterium tuberculosis* (TB). Specifically, it is estimated that more than 11 million people in the United States (U.S.) have latent tuberculosis infection (LTBI), which is about 4% of the total population. While not everyone with LTBI will develop TB disease, about 5% – 10% of infected people will develop TB disease if not treated. This equates to approximately 550,000 to 1,100,000 people who will develop TB at some point in their life, unless they receive adequate treatment.<sup>1</sup> There are several evidence-based treatment regimens available for the

treatment of LTBI, including Isoniazid (INH) and Rifampin (RIF). The INH regimen has two options: a 9-month regimen and a 6-month regimen. However, the 9-month regimen is preferred because it is more efficacious.<sup>2</sup> A 4-month regime of RIF for adults and a 6-month regimen for children is recommended for patients who cannot tolerate INH or who are contacts to patients with INH-resistant TB.<sup>2</sup>

Adherence to treatment required to treat LTBI is challenging considering persons latently infected with *Mycobacterium tuberculosis* are not symptomatic.<sup>3</sup> A review of the literature demonstrates that LTBI treatment completion rates in the U.S. and Canada

generally fall below established targets and have been reported to range from 20% to 65% for a 6-month course of self-administered treatment,<sup>4</sup> well below the national objectives of 79.0%.<sup>5</sup>

Recent studies show that prevalence of positive TB screening test is four times higher in foreign-born persons than in those born in the U.S. In 2008, 20.3 cases of TB per 100,000 population were reported among foreign-born persons living in the U.S.<sup>6</sup> In 2012, in Fayette County, Kentucky (Lexington), 2.9 cases of TB per 100,000 population were reported.<sup>7</sup> Moreover, Fayette County, Kentucky had a net migration rate of 7%, or approximately 1,235 persons, the second highest county rate in the state of Kentucky.<sup>8</sup> The prevention of TB has major public health implications, it is essential to identify and treat those with high risk factors for TB disease.<sup>2</sup> Although the incidents of TB in Fayette County is very low, it is really important for Lexington Fayette County Health Department (LFCHD) as the front line to play the central role in providing essential public health services in communities to treat people with high risk of TB disease. However, there are no recent studies in LFCHD examining LTBI adherence rates and factors associated with completion of treatment for LTBI.

Various factors can be proposed to explain poor adherence for LTBI treatment. Duration of the therapy, concerns about drug toxicity, and pill burden have been attributed to completion of LTBI treatment.<sup>9</sup> Moreover, adherence is particularly challenging among foreign-born persons.<sup>10</sup> Many might not know how to access appropriate care in the U.S. or might not be able to afford care because of lack of insurance or ineligibility for Medicaid. In addition, language and cultural differences can complicate the interaction between foreign-born patients and healthcare providers.<sup>10</sup> Finally, attitudes and behavior related to social stigma and cultural beliefs may also have a

negative impact on the treatment of the disease.<sup>10</sup> However, associations between adherence and patient factors, clinic facilities, and medication regimen characteristics have been found to be inconsistent across studies.<sup>4</sup>

Adherence to LTBI treatment is fundamental in reaching the *Healthy People 2020* goal to reduce TB disease to 1.0 per 100,000 population.<sup>11</sup> Therefore, the purpose of this study was to examine the completion rates among those individuals seeking care at the Lexington-Fayette County Health Department (LFCHD) who started treatment of LTBI with regimens containing INH or RIF and to identify factors associated with completing treatment for LTBI. Specifically this study aims to:

1. Examine the association between patients' demographic characteristics (e.g., sex, age, region of birth, and region of birth) and LTBI treatment completion rates.
2. Assess the influence of treatment length on the completion rate of LTBI treatment.
3. Examine the effect of demographic characteristics and treatment adherence stratified by type of regimen (RIF vs. INH).

Examining completion rates and identifying factors associated with completing LTBI treatment will help public health professionals at the LFCHD to develop appropriate programs addressing barriers among high-risk non-adherent patients and intervene on factors associated with non-adherence to LTBI treatment.

## METHODS

This was a retrospective cohort study utilizing existing de-identified patient data from the LFCHD TB registry. The study protocol and procedures were reviewed and approved by LFCHD Institutional Review Board. The health department's HIPAA rules and regulations were followed.

### 1.1 Study Subject

All LFCHD patients who started treatment of LTBI regimens containing either INH or RIF during July 2012 and estimated to finish the treatment in April 2014 were included in the study sample. Subjects included patients who were screened and referred by non-health department providers for evaluation of a positive TB screening test (TST)/Purified Protein Derivative skin test (PPD) or Interferon – Gamma Release Assays test (IGRAs) as well as those screened directly at the LFCHD clinic and were eligible for LTBI treatment.

### 1.2 Data Collection and Measures

All data were abstracted from existing LFCHD medical records. The diagnosis of LTBI (Figure 1) was based on information gathered from TB screening test result, chest radiographs, physical examination, and in certain circumstances, following the Centers for Disease Control and Prevention (CDC) and the American Thoracic Society (ATS) guidelines published in 2000.<sup>2</sup> In addition, the following information was obtained from the medical charts: socio-demographic characteristics and clinical care (including age, sex, race and ethnicity, country of birth, length of time in U.S.), date of first visit to the clinic, date LTBI treatment started, regimen, LTBI treatment length (in months), interpreter use during clinic visits, employment and risk for TB disease such as contact history and chest X-rays result. The country of birth variable was classified into three regional groups: Asia, representing individuals who were born in Vietnam, Bhutan, Myanmar, China, Iraq, Japan, Korea, Nepal, Pakistan, and the Philippines; Africa, representing those who

were born in Burundi, Cameroon, Congo, Cote D’Ivoire, Ethiopia, Ghana, Liberia, Malawi, Rwanda, and Egypt; and America+Europe, representing those who were born in the U.S., Haiti, Honduras, Mexico, Peru, and Romania.

The outcome variable of interest for the study was completion of LTBI treatment. Those who did not complete the treatment for any reason such as adverse drug reaction (n=9), lost to contact (n=2), physician choose to stop (n=2), client moved (n=4), refused (n=16), TB disease development (n=0), and others (n=1) were also considered non-adherent group.

In the clinic, patients who agreed to start LTBI treatment were prescribed a month supply of LTBI drug (INH or RIF) and vitamin B, if needed, on the same day. They were also scheduled for monthly follow-up appointments for medical evaluation and to receive the next month’s supply of medication. In addition, they were instructed to call and come to the clinic earlier than the scheduled visit if they experienced adverse reactions. In addition to sending a reminder letter, the clinic nurses made two attempts to call patients who did not keep their appointments. If the patients did not respond within two weeks, a home visit was scheduled. Those who failed to return for the medical evaluation after several calls and home visits were considered non-adherent.

The treatment regimen types were INH alone and RIF alone. Patients were considered to have completed the treatment if they took the INH drug daily for 9 months within a 12-month period or 4 months daily of RIF within a

6-month period. In November 2012, the U.S. experienced a severe interruption in the supply of INH which affected TB control nationally.<sup>12</sup> This condition resulted in the LFCHD TB nurses switching several patients who started with INH to the RIF regimen. In this study, we classified those patients as receiving RIF regimen. Moreover, those who took INH treatment for 6 months during the INH shortage were considered completed by the health department. However, in this study, we excluded this type of patient because we were focused on INH as a 9-month treatment (Figure 2).

### 1.3 Statistical analysis

This study examined the relationship between demographic characteristic, TB risk factors, and adherence to LTBI treatment with regimens containing INH or RIF. LTBI treatment rate was calculated as the percentage of persons who completed LTBI treatment containing INH or RIF among those who started the treatment. Completion rates are described by sub categories of demographic and others TB risk factors characteristic. The chi-square was used to examine the relationship between socio-demographic and other TB risk factors with adherence to LTBI treatment. Logistic regression was performed to assess how well the predictor variables explained the adherence to LTBI treatment using all sample. The sample then stratified by LTBI treatment regimen (INH vs. RIF) Logistic regression was rerun. Independent variables that were significantly associated with treatment completion in bivariate analysis were further examined in a multivariate analysis using log

binominal regression. All data were analyzed using IBM SPSS Statistics for Mac, Version 21.0 (IBM corp. Armonk, NY, USA).

## RESULTS

### 1. Study Population

As presented in Table 1, of 110 eligible patients, 59 (50.9%) were male and 46 (41.8%) were female with a mean age of 35.3 years (SD = 0.5). The majority of patients were either immigrants (41.8%) or refugees (45.5%). Only 14 (12.7%) were U.S. citizens or permanent residents.

In terms of the patients' region of birth, 43 (39.1%) were born in Asia, with the majority from Bhutan (13.6%) and Nepal (10.0%). Almost 40% of the patients (37.3%) were born in Africa; Congolese (22.7%) represented the highest proportion of African individuals. Twenty-six patients (23.6%) were born in the America+Europe region. More than three-quarters of the study sample (76%) had lived in the U.S. for less than five years and 75 (71.4%) reported no contact history with TB. Almost 30% of the sample (29.1%) were health workers. Sixty-nine percent of the patients were referred from a private doctor and 30.9% voluntarily attended the health department. In addition, 50 (45.9%) patients required an interpreter during their clinic visits. Less than 60% of the sample (57.3 %) were treated with INH alone and 47 (42.7%) were treated with RIF alone (Table 1).

There were significant differences between the RIF and INH groups with a greater proportion of those less than 24 years of age taking RIF as compared to INH (33.3% vs. 8.5%) and a greater proportion of those who had lived in the U.S. for less than five years receiving RIF as compared to INH (83.3% vs. 66.7%) (Table 1). In addition, a greater proportion of those from the Asian region adhered to treatment as compared to those who did not adhere (44.7% vs. 26.4%) and a greater proportion of treated with INH did not adhere to treatment as compared to



those who adhered (73.5% vs. 50.0%). There were no further differences between LBTI and treatment adherence groups.

## 2. LTBI Treatment Completion.

As presented in Table 1, the overall LTBI completion rate was 76/110 (69.1%). Patients on RIF alone had a higher completion rate than those on INH alone [80.9% vs. 60.3%,  $p = 0.021$ ]. The crude odds ratio of patients based on drug regimen and treatment adherence indicate that those who took RIF had 2.8 times higher odds of adherence to treatment than those on the INH regimen (95% CI, 1.1-6.7). The median time to treatment completion was 270 days (range 6 – 338 days) for INH alone and 123 (range 5 – 189 days) for RIF alone.

Refugees had higher completion rate (48.7%) when compared to immigrants (43.4%) and residents (7.9%); although these differences failed to reach significance ( $p = 0.073$ ). Those who were born in Asia had a higher rate of treatment completion as compared to those who were born in Africa and America+Europe region (44.7% vs. 38.2% vs. 17.1%);  $p = 0.039$ ). In a simple logistic regression, the crude odds ratio of patients based on their region of birth and treatment adherence illustrated that those who were born in the Asian region had a 3.8 times higher odds of adherence to treatment than those who were born in the African and American + European regions (95% CI, 1.3-10.9) (Table 2). When data were stratified based on LBTI treatment groups, patients who were born in Asia had 3.9 times higher odds of adherence to treatment with INH regimen (95% CI, 1.0-14.9) and 3.5 higher with RIF regimen (although not statistically significant 95% CI, 0.6-20.8). When controlling for the region of birth with regimen, patients who were born in Asia region had 3.6 times higher odds of adherence to treatment (95% CI, 1.2-10.7,  $R^2=0.127$ ) (Table 3).

Although there was no statistical significance of chest X-ray result with adherence to treatment in the total sample,

there was a significant relationship in the opposite direction when data was stratified by LBTI treatment regimen. Those in the INH treatment regimen group had 4.0 times higher odds of adherence to treatment if their chest X-ray showed a positive result (CI 95%, 1.2-14.1) (Table 2). On the contrary, those in the RIF treatment regimen group had 0.4 times lower odds of adherence to treatment if their chest X-ray showed a positive result (CI 95%, 0.5-1.0).

## DISCUSSION

In this study, our completion rate of 69.1% is comparable to rates that have been reported in other studies, ranging from 29% – 62%.<sup>3,9,13,15,16,17</sup> Although this completion rate is slightly higher than other studies, it is still below the national objectives of 79.0%.<sup>5</sup> Attitudes in support of treatment completion were found to be associated with better adherence.<sup>4</sup> Thus, in this study, we greatly appreciated the hard work of the TB program officers who have shown their passion in motivating the patients who do not keep the appointment by putting on efforts such as making call, sending post-card reminder and home visiting. We believe that these supporting endeavors contributed to high rate of LTBI treatment adherence. The findings also are consistent with other studies that reported the RIF regimen was independently associated with a 20% higher completion rate than the 9-month INH regimen.<sup>3,4</sup> In our study, we found that those who took RIF had higher odds of adherence to treatment than those on the INH regimen. Although INH therapy is 90% effective for those who complete, its effectiveness is limited by a low adherence rate.<sup>3</sup> A shorter-course treatment may be needed to improve adherence to LBTI treatment regimens. A new short 3-month duration treatment which combines INH with Rifapentine (once per week) and uses directly observed therapy (recommended by CDC<sup>18</sup>) should be considered as an alternative to enhance LBTI treatment adherence rates.

In previous studies, neither age, gender, nor length of time are associated with LBTI treatment completion,<sup>15,16</sup> which is similar to the findings in the present study. Furthermore, in bivariate analyses, we found that the only significant predictor of completion (in addition to the type of regimen) is region of birth. Those who were born in the Asian region had 3.8 times higher odds of treatment adherence as compared to those born in the American/European region in both the total sample and in the INH group. This finding is similar to other studies that have shown those of Asian race were more likely to complete LBTI treatment.<sup>16</sup> However, other studies had failed to find such associations or had inconsistent findings.<sup>4</sup> Yet, when controlling for region of birth with type of regimen in the multivariate analysis, those who were born in Asia were still significantly more likely to complete the treatment as compared to those born in America+Europe.

Although we could not explain other variables that might have been associated with higher completion rate among Asians, our experience during our internship at the LFCHD might be able to provide an answer. Most of the patients were from Asian countries (such as Nepal and Bhutan) and were more likely related to or lived in the same neighborhood as other patients. Therefore, we propose that completing the treatment may have an association with having support from family members and friends. If one of the family members could complete the treatment, he or she may encourage other family members to complete the treatment as well. This phenomenon should be explored further and could potentially be used by LFCHD staff to create a new approach to improve completion rate. We suggest that the health department could have a peer-based intervention that requires family members to accompany the patient at their initial TB clinic visit and medicine pick up. In the clinic, the nurse

can provide appropriate education to the patient and his/her family to complete the treatment emphasizing on the need to prevent all the family from getting TB infection. However, the health department nurses should be trained on how to educate, motivate and counsel the patients and their family in a positive manner.<sup>19</sup> Moreover, annual cultural competency training for the nurses and clinic staff may be warranted.

We also found that treatment adherence among refugees was higher compared to individuals considered immigrants and U.S. residents (37% and 48.7%, respectively). This finding was similar to other studies suggesting refugees are more likely to adhere to TB treatment.<sup>15</sup> While the reason for this finding is unclear, one explanation could be because of administrative reasons. Most of the refugees received care from the Kentucky Refugee Ministries (KRM). KRM assists singles and couples without children in applying for the Wilson-Fish cash and medical assistance program. This program lasts for eight months from their date of arrival. Families with children apply for K-TAP and Passport medical assistance. Both of these programs are temporary and are terminated after the client goes to work.<sup>20</sup> Refugees managed by KRM are required to have a medical check-up upon their arrival in U.S. The supportive services provided by KRM could have been an additional factor influencing LBTI treatment adherence.

Contrary to our expectation, we found that health workers as a high-risk population<sup>2</sup> were proportionally less likely (albeit non-significant) to finish the treatment as compared to non-health workers. Of 32 health workers that initiated LTBI treatment, only 65% completed the treatment. Those who did not complete the treatment mostly fail in the third month of INH and second month of RIF. Because we do not have a qualitative component to this study, we cannot explain why health workers were

less likely to complete treatment. It is important to note that in Lexington, most healthcare facilities require worker candidates to have a TB screen test (TST). However, prior to this policy, the health workers possibly only came to the health department to obtain the TST paperwork, without needing to provide evidence of treatment completion when indicated. Thus, we recommend that health facilities establish policies for both initiating LTBI treatment and requirements for follow-up supervision to enhance health worker adherence.

We postulated that language barriers could be a predictor of non-adherence to LTBI treatment. However, in this study, we did not find any statistically significant association among using an interpreter and treatment completion. At the LFCHD, the clinic uses a telephone-based translation service. Moreover, the TB nurses can also access the telephone-based translator through their cell phone. These activities effectively minimized the language barrier. Moreover, we need to carefully interpret the opposite relationship that had been shown for chest X-ray variable. However, implementing Health Belief model in this study, we believe that this result could be considered as a perceived susceptibility. TB nurses in LFCHD should pay attention for patients with abnormal chest X-ray as vulnerable population and carefully monitor those patients to assure their LTBI treatment completion.

This study is subjected to several limitations. First, the sample size was relatively small to find a significant association among variables; thus, the sample may not be representative of the population of interest. Second, we assumed that all the patients who regularly came to pick up their LTBI medication complied with treatment. Therefore, our outcome variable may be subjected to misclassification bias if patients did not consume medicines as prescribed. Third, because this was a retrospective review,

we were unable to conduct interviews with the patients for certain issues that might have contributed to treatment adherence such as patient education, health insurance, patient beliefs, why the patient did not return to the clinic to pick-up the medication, and the physician's or nurses role in patient compliance with treatment. Fourth, the condition of INH shortage<sup>12</sup> that resulted in LFCHD TB nurses switching several patients who started with INH to the RIF regimen, was believed to be able to affect the completion rate.

Despite these limitations, we believe this study is important for LFCHD programmatic efforts focused on improving LTBI treatment adherence. To our knowledge, this is the first study about LTBI treatment adherence among patients served by the LFCHD; therefore, this study serves as a foundation for more rigorous future research with larger sample size and larger sample scope. The future research, with larger sampling, needs to investigate the association between region of birth and LTBI treatment adherence. Specifically, we believe that having the TB patients who were born in the United States as an independent group and compare it with other regions will probably give interesting result. Moreover, comparing the immigrants and refugees groups, both legally and illegally, will also provide deeper insight of the TB patients' background and barriers.

## CONCLUSION

Reflecting on the high treatment completion rates among people from Asia, we believe that peer-based intervention may be recommended to the LFCHD to enhance LTBI treatment adherence rates. Moreover, one study found that home-based follow-up LTBI patients taking INH was associated with improved treatment completion and no increase in adverse effects regardless of patient characteristics

or prescribed duration of INH therapy.<sup>21</sup> We also recommend new approaches such as integrated community health workers or public health nurses that can deliver care in the patient's home similar to models of prenatal care and LTBI follow-up. Additionally, incentive programs and more flexible appointment scheduling may improve LTBI treatment adherence rates among health department patients. To the researcher, we believe that this study has a lot of benefits for Indonesia, considering Indonesia as one of the countries with high burden of TB disease. With the meticulous study of LTBI and having been witnessed the LTBI process that has been done in the United States, we believe that our knowledge will help Indonesia solving TB burden disease by promoting the prevention with LTBI treatment.

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